

**Amendments to the claims:**

This listing of claims replaces all prior versions, and listings, of claims in the present application:

**Listing of claims:**

Claims 1-71 (cancelled).

72 (previously presented). A method of transferring a gene into a recipient subject, comprising:

- (a) transfected somatic cells *in vitro* with a DNA sequence by chemical or physical techniques to introduce the DNA sequence into the cells;
- (b) screening the resulting transfected somatic cells *in vitro* to select a cell, wherein the selected cell is stably transfected with the DNA sequence so that the selected cell has the permanent capacity to direct expression of the DNA sequence;
- (c) cloning and expanding the selected somatic cell *in vitro*; and
- (d) injecting the resulting transfected, screened, cloned, and expanded somatic cells into the recipient subject;

wherein the DNA sequence comprises the gene and a promoter capable of functioning in the somatic cells; and

wherein, following injection of the transfected, screened, cloned, and expanded somatic cells into the recipient subject, the DNA sequence is incapable of recombining

FINNEGAN  
HENDERSON  
FARABOW  
GARRETT &  
DUNNER LLP

1300 I Street, NW  
Washington, DC 20005  
202.408.4000  
Fax 202.408.4400  
[www.finnegan.com](http://www.finnegan.com)

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with endogenous retroviral sequences, and the DNA sequence is incapable of initiating chronic viral infection in the recipient subject.

73 (previously presented). The method of claim 72, wherein the somatic cells are human cells.

74 (previously presented). The method of claim 73, wherein the human cells are selected from the group consisting of fibroblasts, myocytes, hepatocytes, kidney capsular cells, endothelial cells, epithelial cells of the gut, and pituitary cells.

75 (previously presented). The method of claim 73, wherein the gene encodes a hormone, an enzyme, or a receptor.

76 (previously presented). The method of claim 73, wherein the gene encodes human growth hormone.

77 (previously presented). The method of claim 73, wherein the gene encodes human insulin.

78 (previously presented). The method of claim 73, wherein the transfection comprises calcium phosphate-mediated transfection, microinjection, electroporation, or DEAE-dextran transfection.

79-81 (cancelled).

82 (previously presented). The method of claim 73, wherein the promoter is a regulatable promoter.

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83 (previously presented). The method of claim 73, wherein the DNA sequence further comprises a selectable gene, and wherein the promoter is operably linked to the selectable gene.

84 (previously presented). The method of claim 73, wherein the screening step further comprises screening the resulting transfected somatic cells *in vitro* to select a cell possessing desired expression properties.

85-103 (cancelled).

104 (previously presented). A method of transferring a gene into a recipient subject, comprising:

(a) providing somatic cells;  
(b) transfecting the somatic cells *in vitro* with a DNA sequence comprising the gene and a promoter capable of functioning in the somatic cells, wherein the gene encodes a gene product, and wherein the somatic cells are stably transfected with the gene so that the somatic cells have the permanent capacity to direct expression of the gene upon induction of the promoter;

(c) screening the resulting transfected somatic cells *in vitro* to select a transfected somatic cell, wherein the screening comprises characterizing the transfected somatic cell with respect to expression and regulation of the gene by assaying for translation of the mRNA into the gene product;

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(d) cloning and expanding, *in vitro*, the transfected and screened somatic cell selected in step (c) to form  $10^5$  -  $10^{10}$  transfected, screened, cloned, and expanded somatic cells, and

(e) combining the  $10^5$  -  $10^{10}$  transfected, screened, cloned, and expanded somatic cells with a physiologically acceptable buffer or carrier; and

(f) injecting the resulting transfected, screened, cloned and expanded cell preparation into the recipient subject,

wherein, following injection of the transfected, screened, cloned, and expanded somatic cells into the recipient subject, the DNA sequence is incapable of recombining with endogenous retroviral sequences, and the DNA sequence is incapable of initiating chronic viral infection in the recipient subject.

105 (previously presented). The method of transferring a gene into a recipient subject of any one of claims 73 or 104, wherein the transfected gene encodes human growth hormone.

106 (previously presented). The method of transferring a gene into a recipient subject of any one of claims 73 or 104, wherein the transfected gene encodes insulin.

107 (previously presented). The method of transferring a gene into a recipient subject of any one of claims 73 or 104, wherein the DNA sequence integrates into the chromosome of the selected cell.

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FARABOW  
GARRETT &  
DUNNER LLP

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108 (previously presented). The method of transferring a gene into a recipient subject of any one of claims 73 or 104, wherein the DNA sequence replicates as an extrachromosomal plasmid.

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HENDERSON  
FARABOW  
GARRETT &  
DUNNER LLP

1300 I Street, NW  
Washington, DC 20005  
202.408.4000  
Fax 202.408.4400  
[www.finnegan.com](http://www.finnegan.com)